

Remarks

Claims 1-26, 31-40, 44 and 45 are pending in the application and subject to restriction. Restriction has been required from among four groups of claims identified as follows:

I. Claims 1-25, characterized as drawn to a method of producing a soluble bioactive domain of a protein;

II. Claims 31-34, characterized as drawn to expression constructs for the production of recombinant polypeptides, to a method for producing a fusion polypeptide with a purification tag and to a fusion polypeptide comprising sortase gene product; and

III. Claims 26 and 44-45, characterized as drawn to a method for producing a fusion polypeptide comprising a solubility enhancing tag comprising a SNUIT tag.

The office action fails to group claims 35-40. Based on their subject matter, it is believed that claims 35-40 should have been grouped with Group III. Applicants will respond to the restriction requirement as if claims 35-40 are present in Group III.

Election

Applicants elect the claims of Group III, constituting claims 26, 35-40, 44 and 45. The election is made with traverse, for the reasons set forth below. Applicants reserve the right to request rejoinder of any non-elected claim pursuant to MPEP 821.04.

Traversal of Restriction

Applicants respectfully traverse the finding of lack of unity as it applies to Groups II and III. Examiner alleges that the claims of the application do not relate to a single, general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they allegedly lack the same or corresponding technical feature. Examiner alleges that Zhang *et al.*, Pryor *et al.*, Ton-That *et al.* (described in the office action as "Hung *et al.*"), and Ilangovan *et al.* (described in the office action as "Udayar *et al.*") each disclose "a method of producing a soluble bioactive domain of a protein", thereby allegedly teaching a technical feature linking the claims. Applicants respectfully disagree.

The technical feature linking the claims of Groups II and III is the use of a Sortase gene product as a purification tag. The Group II claims (claims 31-34) are directed to expression constructs for the production of the recombinant polypeptides in which a Sortase gene product is used as a purification tag sequence. As clearly taught by the specification, the SNUT tag (present in claims 44 and 45) is a tag derived from a Sortase gene product (see, for example, page 6, lines 24-26 of the application as filed). As the expression constructs of claims 31-34 comprise a coding region encoding a Sortase gene product as a purification tag sequence, they share the same technical feature as the claims of Group III (claims 26, 44 and 45), *i.e.*, the use of a Sortase gene product as a solubility enhancing purification tag.

None of the cited documents make any reference to Sortase gene products as purification tags. Thus, the common technical feature linking Groups II and III under the terms of PCT Rule 13.1 and PCT Rule 13.2, is novel.

Zhang *et al.* describes the fusion of various proteins to a mutant form of DsbA with no mention of the use of Sortase as a purification tag.

Pryor *et al.* describes expression of soluble protein using a His₆-tag and Maltose-binding-protein double affinity fusion system with no mention whatsoever of the use of a Sortase gene product.

Ton-That *et al.* describes the purification and characterization of Sortase and its use to catalyze surface-protein anchoring. There is no disclosure whatsoever in this document of the use of Sortase as a purification tag or indeed any indication from this document that Sortase could be used for such a purpose.

Ilangovan *et al.* also relates to Sortase and its characterization. The document concentrates in the properties of Sortase in cleaving LPXTG peptides. As with Ton-That *et al.*, no teaching or suggestion whatsoever is made by Ilangovan *et al.* with respect to the use of Sortases as purification tags, as taught by applicants.

The claims of claim Groups II and III share the same special technical feature, *i.e.*, the use of a Sortase gene product as a purification tag. None of the documents upon which the Examiner bases the lack of unity objection makes any reference of the use of Sortase gene products as purification tags. Thus, the common technical feature linking Groups II and III is

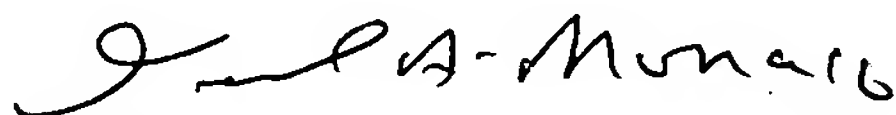
novel. Accordingly, the Examiner is respectfully requested to reconsider the finding of lack of unity, at least insofar as it relates to the claims of Groups II and III.

Remarks Regarding Species Election Requirement

An election of species has been required, but only if Group I is elected. Since Group I is not elected, no election of species is required.

Respectfully submitted,

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